DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 12, 2015

Venus Concept USA Ltd.
Tal Bresler-Stramer, Ph.D., RAC
Vice President Quality Assurance / Regulatory Affairs
4556 North Hiatus Road
Sunrise, Florida 33351

Re: K150161
Trade/Device Name: Venus Viva SR Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II
Product Code: GEI
Dated: April 16, 2015
Received: April 16, 2015

Dear Dr. Bresler-Stramer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K150161

Device Name

Venus Viva SR Device

Indications for Use *(Describe)*

The Venus Viva SR system is intended for dermatological procedures requiring ablation and resurfacing of the skin.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and
Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

510(k) SUMMARY

Venus Concept's Venus Viva SR Device

Sponsor/Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Venus Concept USA Ltd.
4556 N. Hiatus Road
Sunrise, FL 33351
Telephone: 954.572.5585
Fax: 954.572.5680

Contact Person:
Tal Bresler-Stramer, PhD, RAC
VP QA/RA
Venus Concept, Ltd.

Date Prepared: May 11, 2015

Trade Name of Device

Venus Viva SR Device

Classification Name

Electrosurgical cutting and coagulation device and accessories (21 C.F.R. 878.4400; Product Code GEI)

Predicate and Reference Devices

Invasix Ltd.'s Fractora device (K102461) (Primary Predicate)
Reference Devices: Primaeva Medical's Miratone System (K082391), Syneron Medical's eMatrix applicator (K101321), Syneron Medical's eTwo Skin Treatment System (K110672), Venus Concept's Venus Freeze (K111670, K100586) and Venus Swan (K140629, K111784)

Intended Use / Indications for Use

The Venus Viva SR system is intended for dermatological procedures requiring ablation and resurfacing of the skin.

Device Description

The Venus Viva SR device is designed for non-invasive dermatological procedures requiring ablation and resurfacing of the skin. The system is designed to deliver RF energy to the skin in a fractional manner. The device is comprised of a console and an applicator. The applicator is connected to the system via a cable. The applicator (hand piece) includes a detachable electrode tip that is comprised of an array of small electrode pins. The radiofrequency energy is delivered from each of the pins to the tissue, heating the dermal layers beneath the pin with minimal injury to the epidermis layer.

Technological Characteristics

The Venus Viva SR Device has similar technological characteristics to the Fractora device, as both are fractional RF devices comprised of a console and applicator. The technological differences between the Venus Viva SR and its predicate are minor, and the key parameter affecting treatment outcomes (i.e., RF energy per pin) is identical between the devices. Therefore, the dimensional differences or other technical differences between the Viva SR and its predicate do not present any new issues of safety or effectiveness, as demonstrated by the animal study data submitted in support of this 510(k) notice. Therefore, the Venus Viva SR device presents similar technological characteristics as the predicate, in support of substantial equivalence.

Performance Data and Standards

The performance of the Venus Viva SR has been evaluated in testing per the applicable FDA recognized testing standards below.

Electromagnetic Compatibility and Electrical Safety testing was conducted per AAMI/ANSI ES60601-1, IEC 60601-1-2, and IEC 60601-2-2. All results were passing.

In addition, the patient contacting materials (ASTM F899-12b stainless steel, plastic) are biocompatible.

Sterilization parameters were validated per ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11138-1, and AAMI/ANSI ST79. Results demonstrated that the sterilization cycle achieved a sterility assurance level of 10^{-6}.

The Venus Viva SR device also underwent software validation and verification, and results demonstrated that the software was appropriate for release.

Bench testing further confirmed the radiofrequency outputs of the Viva SR are substantially equivalent to those of the predicate.

The device was also evaluated in a porcine study to evaluate the device performance. The study included evaluation of the in vivo and gross necropsy findings. Treatment sites were viewed and scored at Day 0, Day 4, and Day 14 for the presence of erythema, edema, and microneedle pattern, and results were as expected. Skin biopsies were submitted for pathologic review to assess the healing profile at sites following treatment; the treated sites showed skin that was healing well. The test data demonstrated that the Viva SR treatment resulted in the desired therapeutic effects. The results of the study indicated that the Venus Viva SR device exhibited a favorable safety profile and performed as intended in daily observations, adverse events, gross necropsy, wound assessment, and histopathology.

Substantial Equivalence

The Venus Viva SR Device has the same intended use and substantially similar indications for use, technological characteristics and principles of operation as its predicate device. The minor technological differences between the Venus Viva SR Device and its predicate device do not raise any new issues of safety or effectiveness, given that the key energy parameter is the same for the two devices. Animal testing data demonstrate that the Venus Viva SR Device is substantially equivalent to the identified predicate device.

Conclusions

The nonclinical tests outlined above demonstrate that the device performs as intended for dermatological procedures requiring ablation and resurfacing of the skin. Minor differences between the subject and predicate devices do not present any new types of safety or effectiveness questions, as confirmed by device performance. The Venus Viva SR device is substantially equivalent to Invasix Ltd.'s Fractora (K102461).